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TITLE: An Intervention to Control Vasomotor Symptoms for Advanced PC Patients on Hormone Therapy

PRINCIPAL INVESTIGATOR: Michael A. Diefenbach, Ph.D.

CONTRACTING ORGANIZATION: Mount Sinai School of Medicine, New York, NY 10029

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Michael A. Diefenbach

E-Mail: michael.diefenbach@mountsinai.org

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14. ABSTRACT

During the past 12 months, we have received IRB approval from Mount Sinai School of Medicine, the James P. Peters VA Medical Center IRBs, and the Department of Defense. We have also held three focus groups with prostate cancer patients undergoing hormone therapy and multiple research team meetings were held to discuss focus group results, software development, and study protocol. We are currently integrating feedback from the final focus group into the vasomotor symptom intervention (VSI) and plan to run a final focus group to test the usability of the application. Our progress over the previous project period has led us to refine the methodology and software development, and this will allow us to begin the intervention phase during Y2 of the award.

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Project title: An Intervention to Control Vasomotor Symptoms for Advanced PC Patients on Hormone Therapy

Principle Investigator: Michael A. Diefenbach

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Date: 08/02/2012

Summary: Our study team has made great progress during the previous year of our study entitled "An Intervention to Control Vasomotor Symptoms for Advanced PC Patients on Hormone Therapy." During the past 12 months, we have received IRB approval from Mount Sinai School of Medicine, the James P. Peters VA Medical Center IRBs, and the Department of Defense. We have also held three focus groups with prostate cancer patients undergoing hormone therapy and multiple research team meetings were held to discuss focus group results, software development, and study protocol. We are currently integrating feedback from the final focus group into the vasomotor symptom intervention (VSI) and plan to run a final focus group to test the usability of the application. Our progress over the previous project period has led us to refine the methodology and software development, and this will allow us to begin the intervention phase during Y2 of the award. Progress is described in more detail below.

Task 1: Institutional Review Board Process

Protocol and all required documents have been submitted to the Institutional Review Boards (IRB) of Mount Sinai School of Medicine's (MSSM) and the James. P. Peters VA Medical Center (JJP VAMC). After MSSM and James P. Peter VA Medical Center approved the protocols, all approved study materials were submitted to the Department of Defense's Institutional Review Board (IRB). Study personnel updated their required HIPPA and IRB training. In addition to the CITI training at MSSM, all personnel have obtained the following 1) HIPPA authorization, and 2) Privacy and Data Security of MSSM and JJP VAMC. All recruitment personnel have been trained to explain and to obtain informed consent from study participants.

Task 2: Phase I of the software development

In June of 2011, the Principle Investigator met with co-investigators (Dr. Nihal E. Mohamed, Dr. Simon Hall, and Dr. Tracey A. Revenson) and consultants (Kevin Durr, and Dr. William Dudley) to discuss contents of the iPod training, intervention and assessment modules. Based on this meeting we developed the script content and assessments for the vasomotor symptoms paced respiration training, intervention, and assessment modules. During subsequent meetings wire frames (i.e., prototypical mock-ups of the iPod software interface), which contain elements such as animation, music samples, voiceover, and selected actors have been discussed. A contractor composed a short piece of music that will assist with the correcet breathing rhythm. Short video clips were selected to illustrate the breathing pattern visually. Additional features of the software are its ability to track the frequency and duration of hot flashes and to let participants rate the severity of the hot flash they just experienced. A summary screen visualizes all recorded hot flashes within a given week.

Task 3: Refine and finalize Focus Group Guides

Next, the team revised, expanded and finalized the focus group guide and its procedures. The revised guide was submitted and approved by all relevant IRBs. Results of the focus groups have informed the Vasomotor Symptom Intervention (VSI) adoption and its development process.

Task 4: First set of 2 focus groups: preparation, conduct, and analyses

Of the planned focus groups, the first two groups (n = xxx) would mainly focus on the nature of vasomotor symptoms (VS), severity, frequency and their impact on their daily lives. These first two focus groups also gauged the mens' reaction to the breathing intervention techniques. Focus groups were conducted at the JJP VAMC. Men were African American, on average xxx years old, and have been on ADT an average of xxxx months. All suffered from hot flashes of various severities, ranging from mild to severe. The hot flashes were described by patients as being accompanied by profuse sweating, nausea, shivering, head warmth, and dizziness, among other symptoms. There was no consensus on what time of day the hot flashes occur, what may trigger them, and how long they last. While one patient experienced them every day at 5 AM, others say they happen all the time, and yet others claim that it changes every day and there are no specific triggers. Some patients experienced their hot flashes for no more than five minutes while others say they lasted between 10 and 15 minutes. All patients were excited about the potential of a non-pharmacological intervention for VS control.

Task 5: Phase II of the software development

The information from the first two groups was useful in developing the first prototype of the application. Because the duration of the hot flash varies within and between-subjects, this information will be recorded by the application and used for further analysis. When the patient is experiencing a hot flash and starts the paced respiration exercise with the help of the software the application will time how long the hot flash lasted and at what time it occurred. The software will also prompt the user to record how severe ("bad") the hot flash was. This information will then be summarized on a chart for the patient's reference, allowing him to follow trends. Participants in the first two focus groups were also probed about the feasibility of using a breathing exercise application. We realized that men might not always use the software to control their hot flashes and thus we incorporated an additional feature into the application that allows users to record VS information once the hot flash is over. After the patient has experienced a hot flash, he can open the application and select "I Had a Hot Flash," and enter the pertinent information into the application (i.e., time, intensity, and duration of the hot flash.)

Task 6: Second set of 2 focus groups: preparation, conduct, and analyses

The third focus group (n = 6) focused on contents and potential usability of the iPod-based VSI. Again, men were African American, recruited from JJP VAMC, who suffered from VS. We showed a comprehensive layout of the program, including all relevant screens, graphics, videos, and music clips. Participants at first examined the wireframes without further detailed explanation. Men were asked whether they could intuit the functions of different areas of the screen and queried how they would interact with the program. All patients grasped the design

and layout without problems. They stated preferences for certain graphics, videos, and music clips. Suggestions were also given for the "distraction" control group in which the participants will be given several options of games to play rather than the breathing exercise. All completed focus groups were transcribed for analysis and results were incorporated into the final version of the VSI. Results of this focus group were incorporated into the beta version of the study.

Task 7: In Progress

During July 2012 to August 2012, Kevin Durr and his development team will finish finalizing the iPod application. Twelve iPod Touches have been purchased in July 2012 and they are ready for the program to be installed. We expect to start identifying and recruiting participants for usability testing group from both MSSM and JJP VAMC (N=10) to conduct the Beta test early September 2012. All recorded sessions will be transcribed and data obtained from this phase will be used to implement final changes into iPod Touch VSI. During this time, personnel will be trained on the program, and assessment modules. By October 2012, we expect to begin the small randomized feasibility and acceptability trial.